Exhibit 45

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

- - -

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	:	MDL NO. 2875
	:	CIVIL NO. 19-2875 (RBK/JS)
THIS DOCUMENT APPLIES TO ALL CASES	:	HON. ROBERT B. KUGLER

- CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER

VOLUME II

- - -

May 28, 2021

- - -

Continued videotaped remote deposition of JUN DU, taken pursuant to notice, was held via Zoom Videoconference, beginning at 9:12 a.m., EST, on the above date, before Michelle L. Gray, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

- - -

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(Judy Diaz)

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Direction to Witness Not to Answer

PAGE LINE

None.

Request for Production of Documents

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None.

Stipulations

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None.

Questions Marked

PAGE LINE

None.

- - -

THE VIDEOGRAPHER: We are now on the record.

My name is Judy Diaz, I'm a legal videographer for Golkow Litigation Services.

Today's date is May 28, 2021, and the time is 9:12 a.m.

This remote video deposition is being held in the matter of valsartan, losartan, and irbesartan products liability litigation MDL.

This is the continuation of the deponent Jun Du.

All parties to this deposition are appearing remotely and have agreed to the witness being sworn in remotely.

All counsel will be noted on the stenographic record.

The court reporter is Michelle Gray.

The witness and interpreter

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are already under oath.

- - -

... YANG SHAO and EVELYN YANG GARLAND, having been previously duly sworn, translated Chinese to English, as follows:

- - -

... JUN DU, having been previously sworn, was examined and testified as follows:

- - -

CONTINUED EXAMINATION

- - -

BY MR. SLATER:

Q. On the screen we have Exhibit 430.

Let's look at the bottom paragraph on the first page please.

This is your letter to the FDA August 26, 2018.

The bottom paragraph says --

MR. SLATER: I'm sorry. I'll start over.

THE WITNESS: Can you give

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me a few seconds to take a look at this document?

BY MR. SLATER:

Q. Yeah, all right. I didn't even -- I was halfway through my question so I'll start over. But you can go ahead and look first.

MR. SLATER: Keep track of the time, please.

THE WITNESS: I'm ready.

BY MR. SLATER:

Q. Looking now at Exhibit 430, which is your August 26, 2018 letter to the FDA. I want to look at the bottom paragraph on Page 1.

You wrote in this letter, "One of the key questions about this inspection as well as about our own investigation is," quote -- and quoting what the FDA asked -- "'why NDMA was not detected or considered during the process change from the triethylamine process to zinc chloride process.'"

Do you see where that's

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stated at the bottom of the letter?

A. Yes.

Q. One thing I just want to clarify is, in retrospect you also found out that there was NDMA and NDEA from the TEA process, the triethylamine process with sodium nitrite quenching. It turned out that also had the nitrosamine contamination, correct?

A. One, that question was responded at that time. The issue of TEA or NDEA was not discovered yet. Besides NDEA is not a contaminant, it is an impurity rather.

Q. Your response states, "As revealed by our investigation, the ultimate reason for the presence of NDMA in valsartan API is due to this process change in which the solvent dimethylformamide (DMF) was introduced and its impurity/degradant, dimethylamine, unexpectedly reacts with nitrous acid (generated in situ between sodium nitrite and hydrochloric acid)

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during the subsequent quenching step in the presence of the product of that step."

That is what you told the FDA in terms of why the NDMA formed with the zinc chloride process, correct?

A. That is correct. That's what this letter says.

Q. And that change to the zinc chloride process which led to this process impurity of NDMA allowed you, and allowed ZHP, to reduce costs and increase yield for the valsartan API, correct?

A. I believe it should be put in this way. Why we changed the process was to improve the yield and reduce the waste. This would be a process that any API manufacturer would pursue and with the term "fast, effective." This is rather a normal activity or practice.

MR. SLATER: Cheryll, let's digress for a moment and go to Exhibit 312, please, and then we'll come back to this document.

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Let's go if we could, to the cover first.
(Previously marked Exhibit ZHP-312.)
BY MR. SLATER:
Q. Looking at Exhibit 312, this is the FDA establishment inspection report for the inspection from July 23, 2018 to August 3, 2018. Do you see that on the screen?
A. Hold on, let me take a look.
Excuse me, what exhibit number is this?
Q. 312.
A. Thank you. I see it.
Q. Let's go, if we could, to Page 25 of 58; the Bates number at the bottom is Prinston00162373 for that page.
Perfect.
A. Please allow me a few seconds to review this EI report.
MR. SLATER: Keep track of the time, please.
THE WITNESS: I'm ready. I

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just finished reviewing.
BY MR. SLATER:
Q. Looking now at the paragraph, the short paragraph -- rephrase.
Looking at the paragraph in the middle of the page which is reciting the discussions with the FDA investigators, it states in part, "Mr. Jun Du, executive vice president, apologized and stated the change control should have stated the purpose of the change was to save money. Mr. Du further stated the cost reduction was so significant it is what made it possible for the firm to dominant the world market share."
The process change that's being discussed there is the change to the zinc chloride process, correct?
A. Hold on. I'm scrolling to this page.
Yes, I see it. That's what the EI report says.

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Q. Let's go back now to --
A. However, I do not agree with the statement here. I did not make such an apology, and I do not understand why it was written here. I did not state that the cost reduction would cause dominant world market share.
Q. Let's go back to Exhibit 430 please. Let's look now at Page 2 of the letter.
Let's look now at the third paragraph on the page, please. Can you -- rephrase.
Your letter to the FDA states in the third paragraph on Page 2, in the current -- excuse me, I've got to start over.
Looking at Paragraph 3 on Page 2 now, your letter states, "In the current NDMA event, it is not the residual DMF that reacts with nitrous acid of the next step, but rather it is the trace amount of dimethylamine, an impurity/degradant of DMF that reacts

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with nitrous acid to form NDMA, which adds a further dimension over the current thinking, logic and strategy for the evaluation of potential genotoxic impurities. It is this extra dimension over the current industry practice that obscured us from foreseeing this impurity during the process change from triethylamine process to zinc chloride process."
That's what you told the FDA in this letter to try to explain why your company didn't realize when they instituted the zinc chloride process that it would be bringing in a risk of creating NDMA, right?
A. What are you referring to by "the company"?
Q. ZHP, who you were -- who you were writing on behalf of -- rephrase.
ZHP, on whose behalf you were writing this letter as executive vice president.
A. That is correct. That's

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what ZHP wrote.
Q. You signed the letter as executive vice president of the company, right?
A. That is correct. I signed this letter on behalf of ZHP.
MR. SLATER: Let's go now, Cheryll if we could to Exhibit 213, the FDA's response.
(Previously marked Exhibit ZHP-213.
BY MR. SLATER:
Q. On the screen we have Exhibit 213, which is the FDA's November 29, 2018 letter written in response to your August 26, 2018 letter that we were just discussing.
A. Could you give me a few seconds to review this document. I am ready.
Q. First of all, in the middle of the first page the fourth paragraph down states, "We reviewed your August 26, 2018 response in detail and acknowledge

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receipt of your subsequent correspondence."
The August 26th letter is the letter we were just discussing prior to this document, correct?
A. That is correct.
Q. Just above the sentence that I just read, the FDA informed you, on November 29, 2018, "Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to cGMP, your API are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 351(a)(2)(B)."
Do you know what adulterated means?
A. I do.
Q. What does adulterated mean?
A. What they meant was that it was involved in a fraud or fake substance. However, this is their uniform statement in the warning letter.

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If you try to find out what they specifically referred to, you have to resort to the text below.
MR. GOLDBERG: Just note my objection to the last question as calling for a legal conclusion.
BY MR. SLATER:
Q. Going up one more paragraph, there's a single sentence paragraph that says, "This warning letter summarizes significant deviations from current good manufacturing practice (cGMP) for active pharmaceutical ingredients (API)."
And what I'd like to now do is go through one of the specifics. If we can turn now to Page 4 of the letter, which the Bates stamp is ZHP01344162 for that page so we can look at one of the specific examples.
And number -- rephrase.
Number 2, "Failure to evaluate the potential effect that changes in the manufacturing process may have on the quality of your API."

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Again, the change they're talking about here is the change to the zinc chloride process, right?
A. What they discussed here was the zinc chloride process change for valsartan.
Q. The FDA specifically states, "In November 2011 you approved a valsartan API process change (PCRC - 110125) that included the use of the solvent DMF."
That is what occurred as part of the zinc chloride process change, correct?
A. That is correct. It was also approved by the FDA.
Q. Your -- rephrase.
The FDA continues, "Your intention was to improve the manufacturing process, increase product yield, and lower production costs. However, you failed to adequately assess the potential formation of mutagenic impurities when you implemented the new

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process. Specifically, you did not consider the potential for mutagenic or other toxic impurities to form from DMF degradants, including the primary DMF degradant, dimethylamine. According to your ongoing investigation, dimethylamine is required for the probable human carcinogen NDMA to form during the valsartan API manufacturing process. NDMA was identified in valsartan API manufactured at your facility."

And I want to stop there and just confirm, when they talk about NDMA was identified, they are talking about NDMA in the valsartan API that was manufactured with the zinc chloride process, correct?

A. The -- that is correct. The FDA opined here that, retrospectively speaking, after the discovery of the formation of NDMA, the decomposition or degradation of DMF was not considered in the process change. However, when FDA approved this process change, they did

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not consider the degradation of DMF either. Therefore, FDA considered this impurity as an unexpected impurity.

Q. The next paragraph of the letter states -- rephrase.

The next paragraph of the letter from the FDA says, "You also failed to evaluate the need for additional analytical methods to ensure that unanticipated impurities were appropriately detected and controlled in your valsartan API before you approved the process change. You are responsible for developing and using suitable methods to detect impurities when developing, and making changes to your manufacturing processes. If new or higher levels of impurities are detected, you should fully evaluate the impurities and take action to ensure the drug is safe for patients."

And when the FDA pointed out that this was ZHP's manufacturing process, that was correct, ZHP developed the zinc chloride process, implemented

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it, and used it to manufacture the API and finished dose that ZHP sold, correct?

A. What you just read was indeed the content of this warning letter from the FDA.

Could you please repeat your question?

Q. When the FDA refers to your manufacturing processes, that is correct, ZHP developed the zinc chloride manufacturing process, ZHP implemented it, and the API manufactured with that process was sold by ZHP, correct?

A. The process change referred to here was the zinc chloride process change, which was also approved by the FDA and used by ZHP in their manufacturing. Prinston as the ANDA holder also used the API approved by the FDA. Our company also sold this product in the U.S. market.

In addition, with regard to the questions raised in this warning letter from the FDA, ZHP provided their

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own responses to each and every question in this warning letter, including their explanations or clarifications, their own opinions, as well as related improvement actions such as CAPA actions.

If you want to find out the opinion of ZHP, please review the response to this warning letter.

To the best of my personal understanding, FDA accepted our response.

Q. When you refer -- rephrase.

When the FDA refers to your manufacturing processes here, the one that they are specifically talking about is the zinc chloride manufacturing process for valsartan, correct?

A. The manufacturing process referred to in the document we are looking at right now is indeed the zinc chloride process change, judging from the process change number.

Q. The last sentence of this paragraph that states, "If new or higher levels of impurities are detected, you

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should fully evaluate the impurities and take action to ensure the drug is safe for patients."

You agree that ensuring the drug is safe for patients needs to be the most important thing that ZHP should have done, correct?

A. In response to your question, the statement you just quoted was regarding to -- our response to their 483 letter. The FDA's opinion was that our original response was not sufficient. We should continue to evaluate and take corrective actions to ensure the safety of the drugs. That is my personal opinion.

Once again, with regard to all the questions raised in this letter, ZHP had already provided an official or formal response.

Q. The last sentence of this paragraph states, "If new or higher levels of impurities are detected, you should fully evaluate the impurities and

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take action to ensure the drug is safe for patients."

I want to focus on the last part, "ensuring the drug is safe for patients."

Do you agree that is the most important rule that you need to follow, and that ZHP needed to follow, in manufacturing drugs for sale to patients?

MR. GOLDBERG: Objection to form. Misstates testimony.

THE WITNESS: To any drug manufacturer, ensuring the product -- let me put it this way. Let me start all over again.

To any drug manufacturer utilizing their utmost knowledge and effort to ensure the safety to the patient for any of their product is correct.

This statement is correct.

MR. SLATER: Cheryll, I want to go to another document. Don't lose this. We'll come right back

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to it.

I want to go to an article titled Isolation and Identification of Process Impurities in Crude Valsartan. There we go.

Just for the record what exhibit number is this?

MS. CALDERON: 433.

(Document marked for identification as Exhibit ZHP-433.)

BY MR. SLATER:

Q. 433. Thank you.

Looking now at Exhibit 433, this is an article that was published in the Journal of Liquid Chromatography & Related Technologies in 2006.

And if we could, let's go to the second page so we can see who the authors are.

Do you see there's three authors, and the third one is Danhua Wang from ZHP?

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A. I see it.

Q. So this is an article published in 2006 in a medical journal and one of the authors was a ZHP employee. You see that, correct?

A. I see it. However, could you please give me a few seconds to review this document, because I've never seen this document before, nor do I have the relevant technical knowledge.

MR. SLATER: Let's keep time on this.

THE WITNESS: I'm ready.

BY MR. SLATER:

Q. Looking at the introduction to this 2006 article authored in part by a ZHP employee, it starts out stating, "The quality and safety of pharmaceuticals can be significantly effected by the presence of impurities."

Do you see what I just read?

A. That's correct. That's what it says here.

Q. In the case of ZHP's

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valsartan, the quality and safety of the valsartan was significantly affected by the presence of nitrosamine impurities, correct?

MR. GOLDBERG: Objection to form. Vague.

THE WITNESS: Could you please repeat your question?

BY MR. SLATER:

Q. The quality and safety of the valsartan manufactured by ZHP was significantly effected by the presence of nitrosamine impurities, NDMA and NDEA, correct?

MR. GOLDBERG: Objection to form. Vague.

THE WITNESS: I do not agree with your opinion. If we are talking about a product of quality, if the manufacturer manufactures the product, if the process approved by the FDA, and the manufacturing was in compliance with the requirements

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of the GMP, then that product would be considered a product of quality.

As for the safety of a product, it's up to the science to identify and determine the safety.

One, ZHP manufactured this product. FDA did not require us to test NDMA, nor did it set any standard for NDMA.

MR. SLATER: Let's go back to the warning letter please.

Not that warning letter.

Perfect.

BY MR. SLATER:

Q. Looking now -- rephrase.

Going back now to the November 29, 2018 FDA warning letter. Under Section 2, the third paragraph states, "Your response states that predicting NDMA formation during the valsartan manufacturing process required an extra dimension over current industry practice and that your process

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development study was adequate. We disagree. We remind you that common industry practice may not always be consistent with cGMP requirements and that you are responsible for the quality of drugs you produce."

When they refer to the cGMP requirements, as we already talked about on the first page of this letter, the FDA indicated that this warning letter summarizes significant deviations from current good manufacturing practice, cGMP for active pharmaceutical ingredients (API), correct?

A. The first paragraph you just quoted as the FDA's response that all the way to the end, it says the common industry practice may not always be consistent with cGMP requirement. I saw that in the warning letter.

For the second paragraph you just quoted, I could not find where it was in the warning letter. Could you point out where that paragraph came from?

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Q. I just read the third paragraph under Heading Number 2 which states, "Your response states that predicting NDMA formation during the valsartan manufacturing process required an extra dimension over current industry practice and that your process development study was adequate. We disagree. We remind you that common industry practice may not always be consistent" -- actually, you know what, I withdraw that. I just realized what you asked.

The second paragraph I referred to is on the first page of the letter. Let's go back to the first page of the letter.

It's the second paragraph under where it says, "Dear Mr. Du."

It says, "This warning letter summarizes significant deviations from current good manufacturing practice (cGMP) for active pharmaceutical ingredients (API)."

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A. That is correct. The paragraph you just quoted was indeed in this warning letter.
Q. Let's go back to where we were now on the fourth page of the letter.
Where the FDA says, "You are responsible for the quality of drugs you produce," you agree, ZHP is responsible for the quality of drugs that ZHP produces, right?
A. Is this your question or you're merely quoting the warning letter?
Q. I'm asking, do you agree that ZHP is responsible for the quality of drugs that ZHP produces?
A. That is correct. By the time that this last inspection by the FDA took place in 2018, for our manufacturing we passed all the FDA inspections prior to that and it was in compliance with the GMP.
MR. SLATER: Go to Page 6 now of the letter please.

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BY MR. SLATER:
Q. The first full paragraph on Page 6 is a one sentence paragraph that says, "FDA placed your firm on Import Alert 66-40 on September 28, 2018."
That import alert precluded ZHP from selling its valsartan API manufactured with the zinc chloride process into the United States of America, correct?
A. This import ban stopped the manufacturing of API products at our Chuannan facility. Not limited to valsartan. That's a decision made by the FDA.
MR. SLATER: Okay. We can take that document down now.
Let's go to Exhibit 212.
(Previously marked Exhibit ZHP-212.)
MR. GOLDBERG: Adam, if you're in between documents, can we just take a two-minute break, not a long break?

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MR. SLATER: Sure.
MR. GOLDBERG: Thank you.
MR. SLATER: Let's go off the record.
THE VIDEOGRAPHER: The time right now is 10:08 a.m.
We're off the record.
(Short break.)
THE VIDEOGRAPHER: The time right now is 10:12 a.m. We're back on the record.
BY MR. SLATER:
Q. With regard to the November 29, 2018 letter written by the FDA, the FDA was not aware, to your knowledge, that as of at least July 2017, multiple people at ZHP were aware that there was NDMA in the valsartan, correct?
MR. GOLDBERG: Objection to form. Mischaracterizes the document. Assumes facts not in evidence.
THE WITNESS: I do not agree with your opinion.

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Yesterday I've already responded to your questions regarding this topic many times.
BY MR. SLATER:
Q. When you say you don't agree, are you saying that you believe the FDA was aware as of November 29, 2018, that people within ZHP knew, at least as of July 2017, that there was NDMA in the valsartan?
MR. GOLDBERG: Objection to form. Assumes facts. Mischaracterizes the document.
THE WITNESS: Why I do not agree with your opinion, I believe, is that you speculated that ZHP had already known this by 2017.
I have already responded to this lines of questions that the relevant personnel at ZHP responded to FDA's 483 letter or their questions during the inspection truthfully, which is

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ZHP had no knowledge of the existence of NDMA in the valsartan process prior to June 2018.
BY MR. SLATER:
Q. As of November 29, 2018, had ZHP notified the FDA that there were people within ZHP who were aware that there was NDMA in valsartan at least as of July 2017, had that information been provided to the FDA?
MR. GOLDBERG: Objection to form -- objection to form. Assumes facts, mischaracterizes the document, and asked and answered yesterday.
THE WITNESS: This is a hypothetical question you raised. My response to that will remain the same as in my prior response.
BY MR. SLATER:
Q. The answer is no, ZHP had not communicated that information to the FDA as of November 29, 2018, correct?
MR. GOLDBERG: Objection to

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form. Mischaracterizes the document. Assumes facts not in evidence. Asked and answered.
THE WITNESS: My response to this question would be that when ZHP provided the response in 2019 or in 2018, they did that based on our knowledge and the facts.
Your speculation did not stand. Therefore, I don't think it is necessary for me to respond to this question.
BY MR. SLATER:
Q. As of today, May 28, 2021, has ZHP, Huahai U.S., Prinston or Solco -- well, let me rephrase.
As of today, May 28, 2021, has ZHP notified the FDA that as of July 2017 there were people within ZHP who knew there was NDMA in valsartan, yes or no?
MR. GOLDBERG: Objection. Assumes facts not in evidence. Mischaracterizes the document.

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Asked and answered yesterday.
THE WITNESS: You just put your speculation into your question. And I've already responded to that question many times yesterday and today.
With regard to the speculation embedded in your question, I will tell you that ZHP's relevant personnel were not aware of the NDMA existence in 2017. They did not become aware of NDMA until June 2018.
As I said before, for your hypothetical question that was not complete, I would not respond to this question.
BY MR. SLATER:
Q. As of today, May 28, 2021, has ZHP ever notified the FDA about the July 2017 e-mail from Jinsheng Lin or provided that e-mail to the FDA? Yes or no?
A. No.

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Q. As of today, May 28, 2021, has ZHP notified Prinston or Solco or Huahai U.S., about the existence of the July 2017 Jinsheng Lin e-mail or provided that e-mail to those companies?
A. What are you referring to about --
THE INTERPRETER: The interpreter will start all over again.
THE WITNESS: What are you referring to by every company?
BY MR. SLATER:
Q. As of today, May 28, 2021, has ZHP provided the July 27, 2017, Jinsheng Lin e-mail to Prinston, Solco, or Huahai U.S., or advised any of those three companies about the contents of that e-mail? Yes or no?
A. No.
Q. As of today, May 28, 2021, do you intend to provide the July 27, 2017, Jinsheng Lin e-mail to the FDA?
MR. GOLDBERG: Objection to

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form -- objection to form. Calls for privileged information.
You can answer to the extent that you're not going to disclose information that you discussed with your counsel.
THE WITNESS: With regard to this question, it is up to ZHP's QA department, QC department, and other related departments to decide if it is necessary to report that information to the FDA.
It is not up to the CEO to decide whether it is necessary or not.
In addition, Prinston did not receive such information from the finished dose facilities at ZHP.
BY MR. SLATER:
Q. You are the CEO of Prinston, Solco, and Huahai U.S. Therefore, all three of those companies are aware of the

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existence of the e-mail and its contents, correct?
A. Could you repeat your question?
Q. You are the CEO of Prinston, Solco, and Huahai U.S., therefore, since you know about and have read the e-mail, all three companies are fully aware of the content of that e-mail, correct?
A. I do not agree with your statement. That is because even though I became aware of this e-mail last week, I do not know the background and the technical specifics of this e-mail, nor did the QA department, QC department, technology department or the manufacturing department, or any other relevant department at ZHP, provide any explanation to point out whether this was a quality issue or any other type of issue.
I did not receive any official or formal quality assurance feedback through the official channel to

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reflect this is an issue.
In Prinston, Solco and Huahai U.S., the QA department and the regulatory affairs department conduct their daily business based on the information they receive from the official channel.
Q. Have you asked anybody to provide you the background and technical specifics of the July 27, 2017 e-mail from Dr. Jinsheng Lin? Yes or no?
MR. GOLDBERG: Objection to form. Asked and answered yesterday.
THE WITNESS: I have already responded to this question yesterday.
As a CEO, it would not be necessary for me to collect information about the technical specification -- specifics.
For the technical specifics it would be the QA department, QC department, technology department,

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CEMAT, as well as other related departments to conduct an investigation and make a decision accordingly.
This is beyond the scope of my job description or job responsibility.
BY MR. SLATER:
Q. So the answer to my question is no, you haven't asked to be provided that information?
A. The answer to this question would be no. That is because I do not have the technical knowledge to understand. It was also beyond the scope of my job responsibilities.
Q. As the vice chairman of the Board of Directors for ZHP and executive vice president of ZHP, do you want ZHP to disclose the July 27, 2017, Dr. Jinsheng Lin e-mail to the FDA? Yes or no?
MR. GOLDBERG: Objection to form.
THE WITNESS: First of all,

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as a vice chair of the Board of Directors at ZHP, we are at the very high level. We did not participate or get involved in the routine activities. It was up to the corresponding departments, such as the technology department, quality department, or people at the professional level to make such decisions.

Since you mentioned my title of executive vice president, that was just an interim assignment. I was not supposed to manage daily operations and that was beyond my job responsibilities.

BY MR. SLATER:

Q. Is the answer yes, I want that information to be provided to the FDA, or is the answer no, I don't want to provide that e-mail to the FDA? Which one is it?

MR. GOLDBERG: Objection to form.

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THE WITNESS: My answer to your question is that it's up to the ZHP's QA department, QC department, and other related departments to make a decision if a report should be provided to the FDA or not.

BY MR. SLATER:

Q. The right thing to do is to provide that July 27, 2017 e-mail to the FDA immediately, correct?

MR. GOLDBERG: Objection to form. Calls for a legal conclusion.

THE WITNESS: I do not agree with your statement. That is because whether it is the right thing to do or not, I do not have the professional knowledge to make such a judgment.

BY MR. SLATER:

Q. You are the vice chairman of the Board of Directors of ZHP. What is your view as to what the right thing is to do? Is your view that the e-mail should be provided to the FDA? Yes or no?

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MR. GOLDBERG: Objection to form.

THE WITNESS: I already responded to your question just now.

First of all, we do not interfere with the daily operations.

Secondly, the QA department, QC department, CEMAT, and other related departments should make a decision on such technical issues.

BY MR. SLATER:

Q. Do you intend to release the July 27, 2017 e-mail publicly so that the financial markets will be aware of the existence of that document? Yes or no?

MR. GOLDBERG: Objection to form. Relevance.

THE WITNESS: I already responded to your question just now.

My response will remain the same.

BY MR. SLATER:

Q. Is the answer yes, we believe that we should provide that -- rephrase.

Is the answer yes, that as vice chairman of the Board of Directors, I think that the responsible thing to do is to release this information to the financial markets, as you are vice chairman of the Board of Directors of a publicly traded company, or is the answer no, we don't need to release that information?

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MR. GOLDBERG: Objection to form. That question calls for speculation. It's ambiguous and vague.

And you can answer the question.

Let me just note for the record that portion of the

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transcript moving to a protective order of any answers about that.

If another question is posed like that, we'll instruct the witness not to answer. This is going so far outside the scope of what the deposition in this case should be about, and I'm allowing the witness to answer the questions so we get through the deposition.

However, you've now spent the better part of two and a half hours on one document. It's your entire case, I get that.

But it is certainly something that I think Judge Vanaskie would say enough is enough.

MR. SLATER: I have a new question.

THE WITNESS: I need to repeat my answer to your question.

As a vice chairman of the

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Board of Directors, I do not intervene in the specific operations.

As to whether there would be an influence in ZHP's specific actions or whether to take such an action or not, which is to provide a report in the financial market, it depends on the quality department, the technology department, as well as other related departments, as ZHP decide, whether or not to take such an action and whether it is worthwhile to take such an action.

BY MR. SLATER:

Q. Do you believe that the July 27, 2017 e-mail should be made public so that the patients who took the valsartan with the NDMA impurity will be aware of the existence of the document? Yes or no?

A. I do not agree with your statement. That is because with regard

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to this e-mail of 2017, ultimately it's the QA department, QC department, and other related departments to decide how to handle this e-mail.

It does not depend on my personal judgment or speculations, because I do not have the relevant knowledge to do so.

Q. Do you as the vice chairman of the Board of Directors of ZHP, as well as, as the CEO of Prinston, Solco, and Huahai U.S., believe that this e-mail should be made public so that the patients who took the valsartan with the NDMA and NDEA impurity will know about the existence and contents of the e-mail? Yes or no?

A. As a matter of fact I have already responded to this question many, many, many times, as I just did now. Therefore, I would remain the same in my response and I would not repeat that answer.

MR. SLATER: Let's go --

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Cheryll, let's take -- oh. We're actually in this document. Can you go back to the fourth page of this document, please, Exhibit 213?

Perfect.

BY MR. SLATER:

Q. Looking at Exhibit 213, the November 29, 2018, FDA warning letter. I want to look again at the third paragraph under Heading Number 2.

The sentence that states, "Your response states that predicting NDMA formation during the valsartan manufacturing process required an extra dimension over current industry practice and that your process development study was adequate."

With regard to that statement by the FDA characterizing your response, isn't it true that, in fact, the reason that these reactions were not understood from the outset by ZHP was due to insufficient process research and

insufficient study in understanding of genotoxic impurities, isn't that the reason?

A. I do not agree with your statement. In response to the paragraph you just quoted in the FDA's warning letter, ZHP has already provided an official response in writing. I would rather not provide my personal speculation here.

MR. SLATER: Cheryll, let's go to Exhibit 212, please.

BY MR. SLATER:

Q. Exhibit 212 is a draft of the deviation investigation report titled Investigation Regarding an Unknown Impurity (Genotoxic Impurity).

Do you see that on the screen?

A. That is correct.

I would request a few seconds to review this document.

MR. SLATER: Keep time on this, please.

THE WITNESS: I am ready. I have finished the review.

BY MR. SLATER:

Q. Let's go to Section 5.2, the Bates number, the last three digits is 308.

Looking now at Section 5.2 titled Control Strategy. The document states in part, "Due to insufficient extent and depth of process research at the early stage, as well as insufficient study and understanding of potential genotoxic impurities, only side reaction product and degradation products were studied, and was unaware of the further reaction between degradation products and raw material."

That's what this document states, correct?

A. Hold on. I'm scrolling to this page.

I see this document.

Q. That's what the language states, correct?

A. First of all, I don't think this document is an official document. Just it is in the format of a draft.

Q. The information I just read was not what ZHP told the FDA, correct?

A. I don't know, because I do not get involved in the specifics of a deviation investigation.

Q. The information that I just read is not what your letter to the FDA dated August 26, 2018 told the FDA, right?

A. I am not sure because I have not compared the two documents to find out the difference.

MR. SLATER: Cheryll, let's go back to Exhibit 430. Page 2. Third paragraph. The fifth line down.

BY MR. SLATER:

Q. You said, "It is this extra dimension over the current industry practice that obscured us from foreseeing this impurity during the process change

from triethylamine process to zinc chloride process."

That's what you told the FDA, which is very different from what this Document 212 that we just read states, correct?

A. I do not agree with your statement because it says here it requires a more complex -- well, an extra dimension that is more complex research and development.

In the previous document we just looked at, it says the R&D, or research and development, was insufficient, but after all, the reason was the lack of knowledge. Therefore, I believe there is just different ways of description between the two documents.

And in this letter it was more clear in the description of the cause or the reason. In the previous document that we just looked at, the description there was more in general.

I have to emphasize again

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that I do not have the ability to conduct an investigation like the QA department does. I only provide my personal opinion based on the statements in those documents.

MR. SLATER: Let's go back, if we could, to Exhibit 212, where we were.

BY MR. SLATER:

Q. Going back to the language in Exhibit 212, the draft of the deviation investigation report, this very clearly states that the problem was "insufficient extent and depth of process research at the early stage, as well as insufficient study and understanding of potential genotoxic impurities."

That's the language in the document, correct?

A. Well, what you just quoted was indeed what this document says. However, this paragraph continues to say that with the development and progress of science, as well as the in-depth

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understanding of research, the potential genotoxic impurities, this issue is gradually understood.

MR. SLATER: Let's go off the record.

THE VIDEOGRAPHER: The time right now is 11:02 a.m. We are off the record.

(Short break.)

THE VIDEOGRAPHER: The time right now is 11:17 a.m. We're back on the record.

MR. SLATER: Cheryll, let's go to the document ZHP00675949.

What exhibit number is this now?

(Document marked for identification as Exhibit ZHP-434.)

MS. CALDERON: 434.

MR. SLATER: Thank you.

BY MR. SLATER:

Q. Looking now at Exhibit 434, this is an e-mail chain between and among

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some people at ZHP and Charles Wang. Do you see that?

A. Can you give me a few seconds for me to open this document from the link.

MR. SLATER: Time this, please.

THE WITNESS: What document number is this? I do not see it in the link.

MR. SLATER: 434 is the exhibit number.

THE WITNESS: Could you give me a few seconds to review it?

I'm ready.

BY MR. SLATER:

Q. Charles Wang is a toxicologist who was consulted by Min Li, correct?

A. That is correct.

Q. Charles Wang was employed by another company, Glaxo, at the time that he was consulted by Min Li, correct?

A. I'm not sure.

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Q. Did you ever speak to Charles Wang?

A. Yes.

Q. Did you know Charles Wang outside of being introduced to him through Min Li?

A. Could you please repeat your question?

Q. Did you know Charles Wang independently from being introduced to him by Min Li?

Let me ask it differently. Did you meet Charles Wang through Min Li?

A. No.

Q. How did you meet Charles Wang?

A. I met him in a conference.

Q. ZHP consulted Charles Wang because you respected Charles Wang as a Ph.D. toxicologist, correct?

MR. GOLDBERG: Objection to form.

THE WITNESS: What field of work are you referring to when you

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said ZHP consulted him?
BY MR. SLATER:
Q. ZHP consulted Charles Wang with regard to various toxicology questions in 2017 and 2018, correct?
A. I'm not sure about that.
All I know is that ZHP consulted Charles Wang through Min Li on related knowledge to NDMA in valsartan in toxicology.
Q. Looking at Exhibit 319, at the very top of the first page is a July 7th -- rephrase.
Looking at Exhibit 434 at the top of the first page is an e-mail dated November 2, 2018, confirming that Charles Wang was paid for the work he did for ZHP, correct?
A. That's what this e-mail says, but I have never seen this e-mail before.
I do not know whether he has been paid or not either.
Q. This e-mail documents that

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Charles Wang was paid, as of November 2, 2018, for nine reports of 45,000 rmb. That's what the e-mail confirms, right?
MR. GOLDBERG: Objection. Foundation.
THE WITNESS: That is correct. However, I do not know the specifics. That's what this e-mail says.
BY MR. SLATER:
Q. What does 45,000 rmb mean, do you know?
A. It's a simple question, and I would provide a simple answer.
45,000 rmb is the amount in 45,000 rmb.
Q. What does rmb stand for?
A. Rmb stands for the Chinese currency.
Q. What is the equivalent of 45,000 rmb in United States dollars?
MR. GOLDBERG: Objection to form.
THE WITNESS: The exchange

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rate between rmb and U.S. dollar fluctuates with time.
BY MR. SLATER:
Q. Can you give me some approximate idea to the best of your ability right now please. Just to give me a range of what 45,000 rmb would correspond to in U.S. dollars. I'm not holding you to the exact number.
A. Based on the current exchange rate, 1 USD is equivalent to 6.4 rmb based on which you can do a simple calculation.
MR. SLATER: Let's go to Exhibit 319, please.
(Previously marked Exhibit ZHP-319.)
THE WITNESS: Can you allow me to find this document in the link.
I have found it. Can you give me a few seconds to review it?
MR. SLATER: Fine. We keep

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track of all the time. We can take whatever time you need.
THE WITNESS: I'm ready.
BY MR. SLATER:
Q. Looking at Exhibit 319, there is an e-mail from Jim MacDonald, Ph.D., to Charles Wang, following from the back and forth between Dr. MacDonald and Dr. Wang where Dr. Wang had consulted Jim MacDonald.
Do you see that e-mail in the middle of the first page here?
A. I see this e-mail. It is also the first time I see this e-mail.
Q. In this e-mail Dr. MacDonald tells Charles Wang, "I'm afraid I can't be of much help on this case particularly on this time scale. NDMA (or dimethylnitrosamine) is a pretty well-known toxin and animal carcinogen with lots of discussion on permissible levels in drinking water and products. Even though the compound is found in cured meats and some groundwater, the

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body of evidence on this suggest pretty clearly that this is a likely human carcinogen at sufficient exposures. The argument that the company would have to make to keep this product on the market will be very difficult with this profile. I'm not exactly sure where one would begin given the very high levels you think they are seeing. I think the strategy I would probably recommend would be to come up with a CMC plan to remove the contaminant (at least to minimally detectable levels) while they recall the existing product and reformulate. I expect this is not what they would want to hear, but unless there is a compelling reason to leave this product on the market, (e.g., only product available to treat a serious life-threatening disease), I would expect that the FDA would ask for a recall. I would be interested to know what happens at the FDA meeting. These things are always very difficult to predict, but this is

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not a good position for this product in my view. Hope all is well with you. Best regards, Jim."

Do you see what I just read?

A. Yes.

Q. Then up above that, on July 17, 2018, Charles Wang writes to Jim MacDonald and forwards him a link showing that the valsartan had been recalled. Do you see that?

A. Yes.

Q. You were speaking with Charles Wang during this time period, correct, June and July of 2018?

A. That is correct.

Q. And you were aware of the information Charles Wang had and what he had learned from Dr. MacDonald as well, correct?

MR. GOLDBERG: Objection to form. Foundation.

THE WITNESS: I don't know. I do not have the professional knowledge and he would not discuss

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such things with a person that doesn't have professional knowledge like me.

BY MR. SLATER:

Q. Have you seen the deposition testimony given from Min Li?

A. Would you please repeat your question?

Q. Have you seen Min Li's deposition transcript and read what he testified to about your interactions with Charles Wang?

A. No, I've not seen it.

Q. Were you on calls with Charles Wang and Min Li together where all three of you spoke?

A. Are you suggesting that we discussed as a group, the three of us?

Q. Did you, Charles Wang, and Min Li discuss the NDMA contamination of valsartan together on conference calls or in WeChat?

A. First of all, I do not agree with your statement that NDMA is a

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contaminant.

Secondly, I believe there was some discussion among the three of us in WeChat.

MR. SLATER: Take that document down. Let's go to Exhibit 210.

It's not coming up on my screen for some reason. There we go.

BY MR. SLATER:

Q. Looking now at Exhibit 210. This is the deviation investigation report prepared November 5, 2018, according to the front of the document.

This was an official report prepared by ZHP with regard to the nitrosamine contamination of the valsartan, correct?

A. It is about an investigation regarding unknown impurity of valsartan API TEA process.

MR. SLATER: Let's go to Page 11 of 236, please.

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Actually, let's go to Page 10 first, Cheryll.
THE WITNESS: Please allow me some time to scroll to this page.
MR. SLATER: Keep time on this as well please.
THE WITNESS: I am ready.
BY MR. SLATER:
Q. On Page 10, the heading at the top of the page is 3.1.2, NDMA, Physiochemical characteristics and toxicological evaluation of NDMA.
And I'd like to now turn to Page 11. And you can see in the second paragraph there's a citation to an article titled Concise International Chemical Assessment Document 38. N-nitrosodimethylamine, published by the World Health Organization in 2002.
Do you see that citation?
A. Yes.
Q. So this is an official report that was prepared by ZHP citing to

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that article, correct?
A. Judging from what it says in this document, that's correct.
MR. SLATER: Cheryll, is it possible, this might take you a moment, can you try to also pull up Exhibit 204, please.
(Previously marked Exhibit ZHP-204.)
THE WITNESS: Hold on. Let me open this document too, from the link.
MR. SLATER: That's not the version that I have in front of me, marked as 204.
This is a problem. All right.
THE WITNESS: I don't see that.
MR. SLATER: No, take -- take the document down.
All right. Let's go now to Exhibit 321, which is the World Health Organization article that

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was referenced in the deviation investigation report.
This is Exhibit 321.
(Previously marked Exhibit ZHP-321.)
THE WITNESS: Hold on. I don't see that in the link.
Okay. I see it.
Could you allow me a few seconds to review this document?
I am ready, but I cannot understand this document.
BY MR. SLATER:
Q. Let's go to Page 23, please. Top of the page.
A. Hold on. Let me scroll to Page 21.
MR. GOLDBERG: I think it's 23, Jun.
THE WITNESS: I'm ready. I'm on this page.
BY MR. SLATER:
Q. Looking at the top of Page 23 in this article that was cited in

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ZHP's own deviation investigation report, it states in the top right, "Therefore, owing to the considerable evidence of carcinogenicity of NDMA in laboratory species, evidence of direct interaction with DNA consistent with tumor formation, and the apparent lack of qualitative species-specific differences in the metabolism of this substance, NDMA is highly likely to be carcinogenic to humans."
And that language again is found in an article cited by ZHP in its own deviation investigation report, correct?
A. It does not sound the same as the quote you just provided. I did not make the comparison myself.
Q. Are you saying that I didn't read the language accurately?
A. What you just quoted from this document was right.
Q. The World Health Organization article from 2002 concluded

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that NDMA is highly likely to be carcinogenic to humans, correct?
A. Judging from what it says in this document, the statement you just made is correct.
MR. SLATER: Cheryll, can you go back to Exhibit 204, please. I'd like to get to the part where the deviation report, DCE-18001 begins.
THE WITNESS: Hold on. Give me some time to review.
MR. SLATER: You can do whatever you want. I'm just getting to the document where I want to use it.
THE WITNESS: So what's the exhibit number again --
MR. SLATER: 204.
THE WITNESS: What I opened from the link is different from what you're showing on the screen.
BY MR. SLATER:
Q. You need to scroll 12 pages

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in and you'll find this page.
MR. SLATER: Please keep track of all this time. I'm literally going to bring him to one page and identify that the WHO article is identified again. So all this time is unnecessary.
MR. GOLDBERG: Counsel, you keep doing that and it is -- you're the one directing the witness to the documents.
The -- he is scrolling through, and he has told you that he can't find the page you're referring to. Okay.
You've got to give the witness a chance to look at the document and get to the page.
MR. SLATER: Nobody is stopping him from doing that. The page that I'm --
MR. GOLDBERG: This is your time and we're -- and your continual reference to the time,

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you don't have to do it every single time the document goes up. Your people are taking -- keeping that time.
THE WITNESS: Can you repeat the exhibit number? I go to Exhibit 204, but the one that I see is different from what you have shown.
BY MR. SLATER:
Q. This is the exhibit. It's Page 12 of the exhibit.
A. I would like you to tell me the exhibit number again? What's the number, 200 and what?
MR. SLATER: I can't do this. Cheryll, can you help him, please?
MS. CALDERON: Mr. Du, it's page -- Exhibit 204, ZHP Exhibit 204.
And then you can just -- you can actually just go to the little box at the top that says "of 120."

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You can put in the number 12.
This is the front of the page. Then you just scroll down to the 12th page.
Do you see that? Right there.
THE WITNESS: I see it. I see it. We are on different pages.
MS. CALDERON: Yes.
THE WITNESS: Now I see it.
BY MR. SLATER:
Q. Looking within Exhibit 204, is the deviation investigation report dated July 20, 2018, it's entitled Investigation regarding a Suspected Genotoxic Impurity of Valsartan, DCE-18001.
Do you see that?
A. Yes.
MR. SLATER: Cheryll, please turn to Page 24 of 33 within this -- this document. It's ZHP0004388.

BY MR. SLATER:
Q. Looking at the bottom paragraph on this page, there is a citation to the World Health Organization article from 2002 that we just looked at. Do you see that?
A. Please allow me to scroll to this page before answering your question. I'm ready.
Q. Do you see that the World Health Organization article from 2002 is cited in the ZHP deviation investigation report that we're looking at?
A. Yes.
Q. And that's in the section titled 4.1.2, Probable Routes of Human Exposure and Average Daily Intake/Exposure From Environment.
Do you see that's the heading at the top of the page?
A. Yes.
Q. And again, that World Health Organization article that is cited in your company's official report concluded

that NDMA is highly -- highly likely to be carcinogenic to humans. We just went over that, correct?
A. That is correct.
MR. SLATER: Thank you. I have no further questions at this time, subject to my right to request continuation or additional testimony based on motion practice subsequent to the deposition.
Thank you.
MR. GOLDBERG: We'll take a few minute break and then we'll come back in. Can we go off the record for a few minutes?
THE VIDEOGRAPHER: The time right now is 11:52 a.m. We are off the record.
(Short break.)
THE VIDEOGRAPHER: The time right now is 12:05 p.m. We're back on the record.
MR. GOLDBERG: We have no questions for the witness at this

time. Thank you.
MR. SLATER: Okay. Thanks everybody.
THE VIDEOGRAPHER: The time right now is 12:06 p.m. We are off the record.
(Excused.)
(Deposition concluded at approximately 12:06 p.m.)

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, JUN DU, have the opportunity to read and sign the deposition transcript.

MICHELLE L. GRAY,
A Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter and Notary Public
Dated: June 2, 2021

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, 217 - 301, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

JUN DU DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

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Notary Public

LAWYER'S NOTES

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